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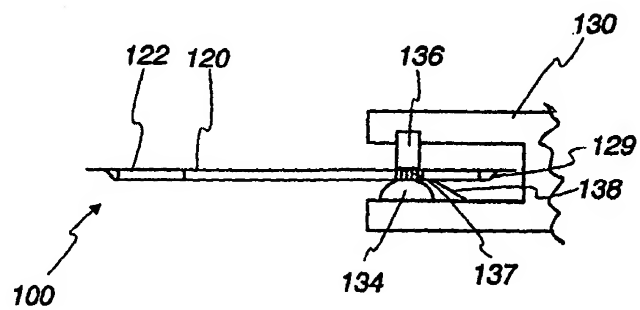
# (54) Packaging system for test sensors

(57) A testing device for analyzing the glucose concentration of a sample of blood is adapted to remove a test sensor from a sensor package. The testing device comprises an inlet region and a puncturing member. The inlet region receives a portion of the sensor package extending inward from an outer periphery of the test sensor package. The puncturing member is adapted to extend into the inlet region, puncture the sensor package, and to engage a mating feature of the test sensor. The puncturing member is adapted to hold the test sensor in the inlet region in a manner allowing the package to be removed and is adapted to hold the test sensor in the inlet region during testing a blood sample.

*Fig. 6*



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**Description**

## FIELD OF THE INVENTION

**[0001]** The present invention relates generally to blood glucose monitoring systems for determining the concentration of glucose in blood, and more particularly, to a test sensor packaging system for use with blood glucose monitoring systems.

## BACKGROUND OF THE INVENTION

**[0002]** It is often necessary to quickly obtain a sample of blood and perform an analysis of the blood sample. One example of a need for obtaining a sample of blood is in connection with a blood glucose monitoring system, which a user must frequently use to monitor the user's blood glucose level.

**[0003]** Those who have irregular blood glucose concentration levels are medically required to regularly self-monitor their blood glucose concentration level. An irregular blood glucose level can be brought on by a variety of reasons including illness such as diabetes. The purpose of monitoring the blood glucose concentration level is to determine the blood glucose concentration level and then to take corrective action, based upon whether the level is too high or too low, to bring the level back within a normal range. The failure to take corrective action can have serious implications. When blood glucose levels drop too low - a condition known as hypoglycemia - a person can become nervous, shaky, and confused. That person's judgment may become impaired and that person may eventually pass out. A person can also become very ill if their blood glucose level becomes too high - a condition known as hyperglycemia. Both conditions, hypoglycemia and hyperglycemia, are potentially life-threatening emergencies.

**[0004]** One method of monitoring a person's blood glucose level is with a portable, hand-held blood glucose testing device. The portable nature of these devices enables the users to conveniently test their blood glucose levels wherever the user may be. The glucose testing device includes a test sensor to harvest the blood for analysis. One type of test sensor is the electrochemical biosenors. The electrochemical biosensor includes a regent designed to react with glucose in the blood to create an oxidation current at electrodes disposed within the electrochemical biosensor which is directly promotional to the users blood glucose concentration. Such a test sensor is described in U.S. Patent Nos. 5,120,420; 5,660,791; 5,759,364; and 5,798,031, each of which is incorporated herein in its entirety. Another type of sensor is an optical biosensor, which incorporates a reagent designed to produce a colorimetric reaction indicative of a users blood glucose concentration level. The colorimetric reaction is then read by a spectrometer incorporated into the testing device. Such an optical biosensor is described in U.S. Patent No. 5,194,393, which is incorporated herein by reference in its entirety.

**[0005]** In order to check the blood glucose level, a drop of blood is obtained from the fingertip using a lancing device, and the blood is harvested using th t st s n-sor. The test sensor, which is inserted into a testing unit, is brought into contact with the blood drop. The test sensor draws the blood, via capillary action, to the inside of the test unit which then determines the concentration of glucose in the blood. Once the results of the test are displayed on a display of the test unit, the test sensor is discarded. Each new test requires a new test sensor.

**[0006]** Referring now to FIGS. 1 and 2, an example of a testing device 10 and a package 30 of test sensors 12 ("sensor pack") are shown, respectively. The sensor pack 30 is designed to be housed within the testing device 10. Prior to each test, a collection end 14 of an individual test sensor 12 is pushed by a mechanism within the testing device 10 through its packaging and is extended from the test device 10 through a slot 16 for harvesting a sample of blood. The testing device includes a slider 18 for advancing the test tensor 12. In FIG. 1, a test sensor 12 is shown extending from the testing device 10. The collection end 14 extends from the testing device 10, while a contact end, that is the opposite end of the test sensor 12, remains inside the testing device 10. The contact end includes terminals that electrically couple the electrodes to a meter disposed within the testing device 10 for measuring the oxidation current produced at the electrodes by the reaction of glucose and the reagent. The test unit includes a display 20.

**[0007]** Referring now to FIG. 2, test sensors 12 are shown disposed in the sensor pack 30. The sensor pack 30 is made up of a circular disk 32 having ten individual compartments (blisters) 34 arranged radially. The disk is made from an aluminum foil/plastic laminate which is sealed to isolate the sensor from ambient humidity and from other sensors with a burst foil cover 36. Each test sensor 12 kept dry by a desiccant located inside a desiccant compartment 37 disposed adjacent the blisters 34. To retrieve a sensor, a mechanism disposed within the testing device 10, such as a knife, is driven down through the burst foil into an individual elongated compartment 34 at the end closest to the hub of the disk 32 and then moved radially toward the perimeter of the blister 34 In doing so, the knife engages the contact end 38 (fish tail) of the sensor in that compartment Radial travel of the knife pushes the tip of the sensor out through the burst foil and through parts of the testing device 10 such that the collection end of the sensor 12 is completely out of the testing device 10 and ready to receive a fluid test sample such as blood. For this stage, it is essential that the bond between the base and lid of the sensor withstand the sheer forces generated when the sensor bursts out through the foil. This method of providing a sensor ready for use is more fully described in U.S. Patent No. 5,575,403, which is incorporated herein by r f-erence in its entirety.

**[0008]** Further details of the operational and mechan-

ical aspects of the testing device 10 and sensor pack 30 are more fully described in U.S. Patent Nos. 5,575,403; 5,630,986; 5,738,244; 5,810,199; 5,854,074; and 5,856,195, each of which are hereby incorporated by reference in their entireties.

**[0009]** A drawback associated with testing devices which house a package of sensors is that the size of the package (*i.e.*, the number of sensors in the package) is constrained by the device itself, thus making it difficult to modify the number of sensors per package. Accordingly, there exists a need for a testing system wherein the test sensor package size is independent of the testing device.

**[0010]** A drawback associated with the test sensor 12 of the device illustrated in FIGS. 1 and 2 is the somewhat pointed collection end (FIG. 2) of the 14 of the test sensor 12. The pointed end can be inconvenient and uncomfortable in collecting blood. The collection end 12 is pointed to puncture the foil cover 36 as the test sensor 12 is pushed from its individual compartment 34. A test sensor which has a substantially flat, non-pointed, collection end would more conveniently and comfortably collect a sample of blood.

## SUMMARY OF THE INVENTION

**[0011]** A testing device for analyzing the glucose concentration of a sample of blood is adapted to remove a test sensor from a sensor package. The testing device comprises an inlet region and a puncturing member. The inlet region receives a portion of the sensor package extending inward from an outer periphery of the test sensor package. The puncturing member is adapted to extend into the inlet region, puncture the sensor package, and to engage a mating feature of the test sensor. The puncturing member is adapted to hold the test sensor in the inlet region in a manner allowing the package to be removed and is adapted to hold the test sensor in the inlet region during testing a blood sample.

**[0012]** The above summary of the present invention is not intended to represent each embodiment, or every aspect, of the present invention. Additional features and benefits of the present invention will become apparent from the detailed description, figures, and claims set forth below.

## BRIEF DESCRIPTION OF THE FIGURES

**[0013]** Other objects and advantages of the invention will become apparent upon reading the following detailed description in conjunction with the drawings in which:

FIG. 1 is a perspective view of a prior art testing device;

FIG. 2 is a perspective view of a prior art sensor pack having a foil lid removed;

FIG. 3 is a perspective view of a lid and a base plate of a single test sensor according to the pr sent invention

FIG. 4 is a side vi w of a test sensor pack for a single test sensor according to the present invention;

FIG. 5 is a top view of a test sensor pack for a single test sensor according to the present invention;

FIG. 6 is a side view of a test sensor pack inserted into a testing device according to the present invention;

FIG. 7 is a side view of a test sensor inserted into a testing device according to the present invention;

FIG. 8 is a side view of a stack of test sensors according to the present invention;

FIG. 9 is a side view of a sensor pack dispensing mechanism according to the present invention; and

FIG. 10 is a test sensor pack card according to the present invention.

## DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

**[0014]** Referring now to FIGS. 3, 4, and 5, a single sensor pack 100 for a single test sensor is shown. The sensor pack 100 includes abase 102 and a foil cover 104. The base 102 includes a test sensor cavity 106 one end of which comprises a desiccant cavity 108. In the illustrated embodiment, the test sensor cavity 106 is shown separated by the desiccant cavity by a dashed line 110. In an alternative embodiment of the present invention, the dashed line may represent a raised portion such as a wall that maintains a desiccant 122 (FIG. 5) and a test sensor 120 (FIG. 5) in their respective cavities. Such a wall should be sized to still allow vapor communication between the desiccant cavity 108 and the test sensor cavity 106 so that the desiccant may properly maintain the humidity of the test sensor cavity 106 as is described in greater detail below.

**[0015]** The foil cover 104 is adapted to cover the base 102 and to be affixed to the base 102 by sealing along the entire outer peripheral edge of the foil cover 104 to an outer peripheral edge 112 of the base 102. The foil cover 104 may be made of any material that will adequately seal the test sensor and desiccant cavities 106, 108 while providing a material than can be easily severed when extracting a test sensor 120 from the sensor cavity 106 as is described below. According to one embodiment of the present invention, the foil cover 104 is made out of AL-191-01 foil distributed by alGroup Wheaton.

**[0016]** The test sensor pack 100 is constructed so that the test sensor cavity 106 is in vapor communication with the desiccant cavity 108. The desiccant cavity 108 is formed of a small depression in the base 102 adjacent the test sensor cavities 106. A desiccant material is disposed in the desiccant cavity 108 in order to maintain the test sensor cavity 106 at an appropriate humidity level so that the reagent material disposed within the test sensor 120 is not adversely affected prior to being used.

The desiccant material 122 is in the form of a small bag or round bead of material or any other form that can be readily disposed in the desiccant cavity 108. The amount of such desiccant material placed in the desiccant cavity 108 will be dependent on the amount that is required to maintain the sensor cavity 106 in a desiccate state. One type of desiccant material that can be used is 13X synthetic molecular sieves from Multisorb Technologies Inc. of Buffalo, New York, available in powder, pellet, and bead forms.

**[0017]** Referring now to FIGS. 4 and 5, a side view of a sensor pack 100 and a top view of the sensor pack 100 (with the foil cover 104 removed) are shown, respectively, having a test sensor 120 disposed within the sensor cavity 106 and a desiccant 122 disposed within the desiccant cavity 108. The test sensor 120 is disposed within the sensor pack such that a collection end 124 of the test sensor 120 is disposed adjacent the desiccant cavity 108. A contact end 126 of the test sensor 120 is disposed towards the end of the test sensor pack 100 opposite the desiccant cavity 108. The test sensor collection end 124 includes a capillary inlet (not shown) for collecting a sample of blood. The test sensor contact end 126 includes terminals (not shown) for electrically coupling electrodes within the test sensor 120 to a testing device. The base 102 has an angled side wall 129, which facilitates the removal of the test sensor 120 from the sensor pack 100 as described below.

**[0018]** According to the embodiment of the sensor pack illustrated in FIGS. 4 and 5, the sensor pack 100 has a width $W_1$ of approximately 0.445 inches (about 11.30 mm), a length $L_1$ of approximately 1.170 inches (about 29.7 mm), and a height $H_1$ of approximately 0.038 inch (about 0.97 mm).

**[0019]** Referring to FIGS. 6 and 7, the removal of the test sensor 120 from the sensor pack 100 will be described. In operation, a testing device 130 is adapted to remove the test sensor 120 from the sensor pack 100. To load a test sensor 120, the sensor pack 100 is orientated with the contact end 126 of the sensor facing towards the testing device 130, and then the sensor pack 100 is pushed into the testing device 130 as shown in FIG. 6. A guide member 134 aides in the proper alignment of the sensor pack 100 within the testing device 130. Once the sensor pack 100 is pushed into the meter, a puncturing member such as a pin 136 is lowered by the testing device 130 such that it punctures the foil cover 104 and engages a mating component 137 of the test sensor 120. In the embodiment of the test sensor 120 illustrated in FIG. 5, the mating feature is an indentation 137 disposed in the test sensor 120. The pin 136 engages the test sensor 120 and presses the test sensor 120 against the guide member 134. The sensor pack 100 is then pulled away from the testing device 130 by the user, the pin 136 holds the sensor stationary against the guide member 134 causing the sensor 120 to burst out of the inward (toward the testing device 130) nd of the sensor pack 100. As the sensor pack 100 is pulled away, the sloped side wall 129 of the base 102 drives the contact end 126 of the test sensor 120 against the foil cover. The contact end 126 of the test sensor 120, illustrated in FIG. 5, is pointed so that the test sensor 120 can more easily puncture the foil cover 104 and "burst" out of the sensor pack 100. The test sensor 120 is now in a testing position (FIG. 7) and is ready to be used to collect and analyze a sample of blood.

**[0020]** The testing device is designed so that once the package is removed, the test sensor 120 is properly aligned in the testing device 130 to conduct the test. The testing device includes terminals 138 that electrically couple the testing device 130 to the terminals (not shown) disposed on the test sensor 120. Once the test sensor 120 is in the testing position, the collection end 126 of the test sensor 120 is placed into a sample of blood, such as a sample of blood that is accumulated on a person's finger after the finger has been pricked. The blood is absorbed into the test sensor 120 and chemically reacts with the reagent material in the test sensor 120 so that an electrical signal indicative of the blood glucose level in the blood sample being testing is supplied to the terminals 138 and thereby to a meter disposed within the testing device 130 for measuring the electrical signal. The result of the analysis, that is the blood glucose level of the sample tested, is communicated to the user via a display (not shown) disposed on, or coupled to, the testing device 130.

**[0021]** The testing device 130 and sensor pack 100 illustrated in FIGS. 6 and 7 is advantageous over many prior art test sensors because the sample collection end 124 of the test sensor 120 never contacts or passes through the testing device 130. This arrangement removes the potential risk of cross-contamination in situations where the testing device 130 may be used by more than one patient.

**[0022]** As discussed in the background section, the testing device 130 and sensor pack 100 are advantageous because the sensor pack 100, or the number of sensor packs 100, are independent of and are not constrained by the size of the testing device. For example, referring to the prior art shown in FIGS. 1 and 2, the size of the sensor pack 30 is constrained by the size of the testing device 10, because the sensor pack 10 is housed within the testing device 10. Accordingly, it would appear to be difficult to modify the design of the sensor pack 30 to have more than the ten test sensors 12 disposed within the sensor pack 30.

**[0023]** Referring now to FIG. 8, a sensor pack stack 150 is shown. The sensor pack stack 150 is made up of a plurality of sensor packs 100 stacked one top of one another. While the sensor pack stack 150 illustrated in FIG. 8 comprises twenty-five test sensors 100, other sensor pack stacks can include any number of test sensors 100 because a sensor pack stack (of any siz ) will not be housed within the testing device 130. Th sensor stack pack 150 comprising twenty-five test s nsors 120 has a height $H_2$ of approximately one inch (about 25.4

mm). The inventor envisions that, in accordance with the present invention, the sensor packs 100 will be commercially available in sensor stack pack stacks of a variety of sizes. In an alternative embodiment, loos sensor packs 100 are commercially available in a container such as a box or bag.

**[0024]** Referring now to FIG. 9, a sensor pack dispenser 160 is shown. The dispenser 160 is adapted to house a sensor pack stack 150 and to dispense individual sensor packs 100. The dispenser 160 includes a housing 162 and an outlet 164 in the housing 162 through which the individual sensor packs 100 are dispensed. The sensor packs 100 are dispensed such that the contact end 126 of the test sensor 120 disposed with the sensor pack 100 is extended through the outlet 164. According to one embodiment, the end of the sensor pack corresponding to the contact end 126 is pushed directly into the testing device. Within the dispenser 160, the stack 150 rests on a platform 166 which is pressed upward by a spring 168. In order to dispense an individual sensor pack 100, a plunger 170 is depressed, which forces the uppermost sensor pack 100 through the outlet 164 as shown in FIG. 9. A spring 172 moves the plunger 170 to its home position (not show, to the left as viewed in FIG. 9) to make way for the spring 168 to move the platform 166, and in turn the stack 150, upward. At this point, depressing the plunger 170 would dispense a new sensor pack 100.

**[0025]** Referring now to FIG. 10, a card 180 having a plurality of sensor/desiccant cavities 182 is shown. While a sensor pack card 180 may contain any number of test sensors 120, the card 180 illustrated in FIG. 10 holds twenty test sensors and has a length $L_3$ of approximately 3.64 inches (about 92.46 mm) and a width $W_3$ of approximately 2.25 inches (about 57.15 mm). According to one embodiment, the card 180 is made of a single base 184 having a plurality of sensor/desiccant cavities 182 disposed therein and a single foil cover. In such an embodiment, the foil cover is heat sealed to the outer peripheral edges of the base and about the perimeter of each set of the sensor/desiccant cavities disposed in the base to isolate each of the sensor/desiccant cavities from each other. Each of the test sensors 120 are disposed in the card 180 such that the contact end 126 is disposed adjacent the outer periphery of the card 180. This arrangement allows the card 180 to be pushed into the testing device (FIGS. 6 and 7) to extract a test sensor 120 from the card.

**[0026]** While the present invention has been described and illustrated in connection with electrical biosensors, the present invention is applicable to other types of test sensors including optical biosensors. As discussed in the background section, optical biosensors are described in U.S. Patent No. 5,194,393, which is incorporated herein by reference above. Additionally, the present invention is applicable to other configurations of biosensors, such as biosensors that do not have a contact area and a collection area disposed at opposite ends of the test s nsor, but hav the collection area disposed on other areas of the test sensors including on the side or on th top of the test sensor. Regardless of the type of sensor employ d in the analysis, the present invention provides the described advantages to the overall testing process.

**[0027]** While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof have been shown by way of example in the drawings and herein described in detail. It should be understood, however, that it is not intended to limit the invention to the particular forms disclosed, but on the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

## Claims

1. A method for loading a test sensor disposed within a sensor package into a blood glucose testing device, the method comprising:

   inserting a portion of the sensor package into an inlet region of a blood glucose level testing device;
   lowering a puncturing member of the test device into the inlet region;
   puncturing the test sensor package with the puncturing member;
   engaging the test sensor disposed within the sensor package with the puncturing member;
   holding the test sensor in the inlet region with the puncturing member; and
   removing the sensor package by pulling a second end of the sensor package in a direction away from the testing device.

2. The method of claim 1 wherein the test sensor is an electrical biosensor, the electrical biosensor having a contact end and a collection end, the contact end disposed toward an outer periphery of the sensor package, and wherein inserting further comprises inserting the portion of the sensor package corresponding to the outer periphery of the sensor package, the inserted portion corresponding to the contact end of the test sensor.

3. The device of claim 1 wherein the end of the test sensor includes a contact area located on a first side of the test sensor and a collection area located along another side of the test sensor, the test sensor being disposed within the sensor package such that the contact area is disposed adjacent the outer periphery of the s nsor package.

4. The method of claim 1 wherein the test sensor is an

electrical biosensor having a contact area and a collection area.

5. The method of claim 1 wherein the step of removing further comprises electrically coupling a pair of terminals disposed in the inlet region of the testing device to a pair of terminals disposed on the test sensor.

6. A testing device for analyzing the glucose concentration of a sample of blood adapted to remove a test sensor from a sensor package, the sensor package containing at least one test sensor, the testing device comprising:

an inlet region for receiving a portion of the sensor package extending inward from an outer periphery of the sensor package, the received portion of the sensor package corresponding to an end of the test sensor disposed in the sensor package; and
a puncturing member adapted to extend into the inlet region, puncture the sensor package, and to engage a mating feature of the test sensor disposed towards the end of the test sensor, the puncturing member being adapted to hold the test sensor in the inlet region in a manner allowing the package to be removed, the puncturing member being adapted to hold the test sensor in the inlet region during testing a blood sample.

7. The device of claim 15 wherein the test sensor is an electrical biosensor.

8. The device of claim 16 wherein the end of the test sensor is a contact end and an opposite end of the test sensor is a collection end, the test sensor disposed within the sensor package such that the contact end is disposed adjacent the outer periphery of the sensor package.

9. The device of claim 16 wherein the end of the test sensor includes a contact area located on a first side of the test sensor and a collection area located along another side of the test sensor, the test sensor being disposed within the sensor package such that the contact end is disposed adjacent the outer periphery of the sensor package.

10. The device of claim 16 wherein the electrical biosensor includes a contact area and a collection area.

11. The testing device of claim 15 further comprising a pair of t rminals dispos d in the inlet region adapted for lectrically coupling a pair of terminals disposed on the test sensor to the blood glucose testing device.

Fig. 1
(prior art)

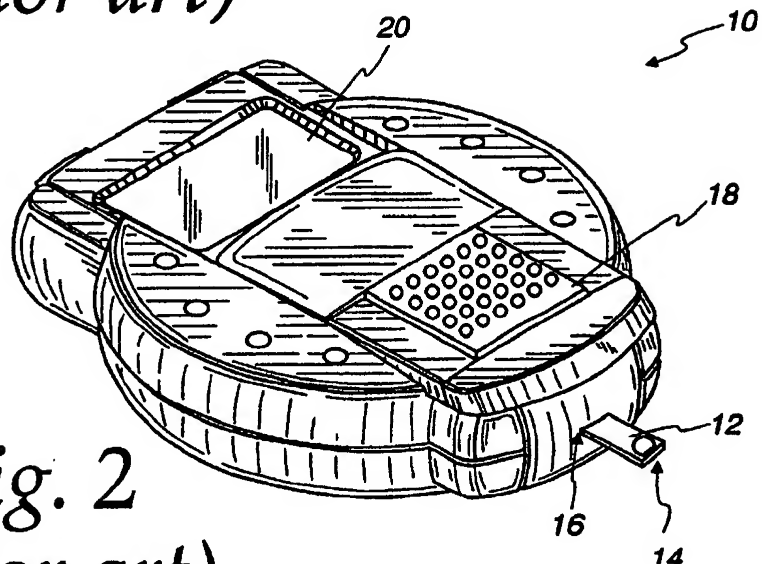



Fig. 2
(prior art)

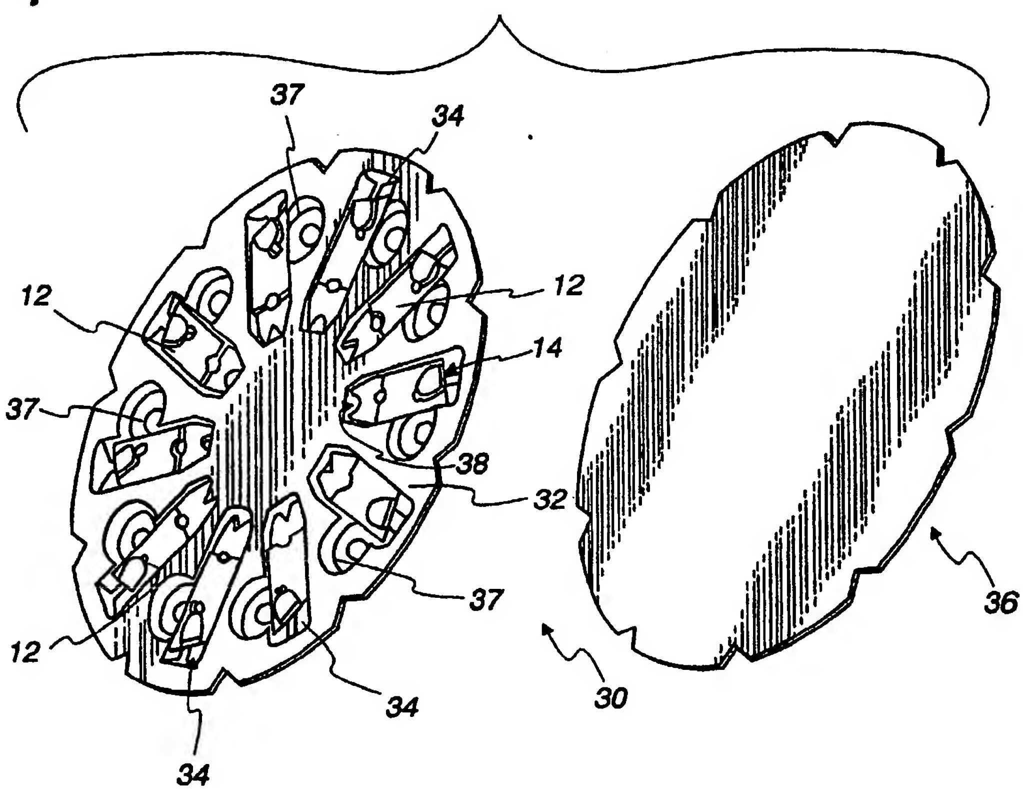


*Fig. 3*

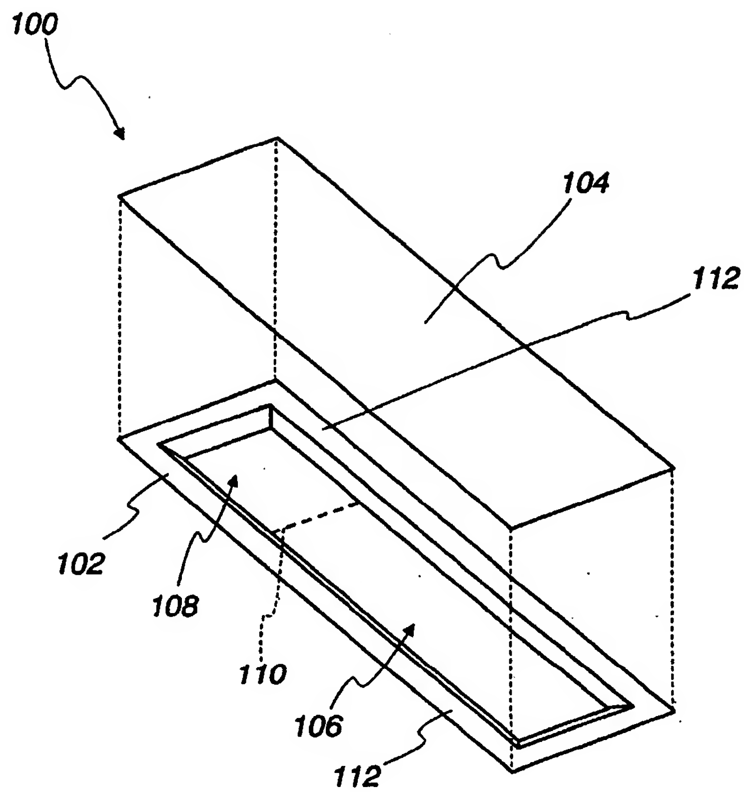


Fig. 4

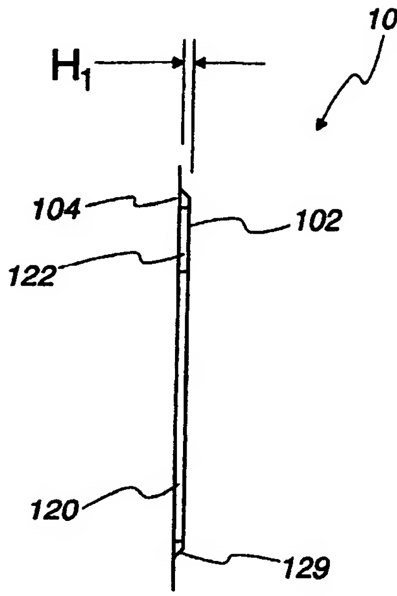



Fig. 5

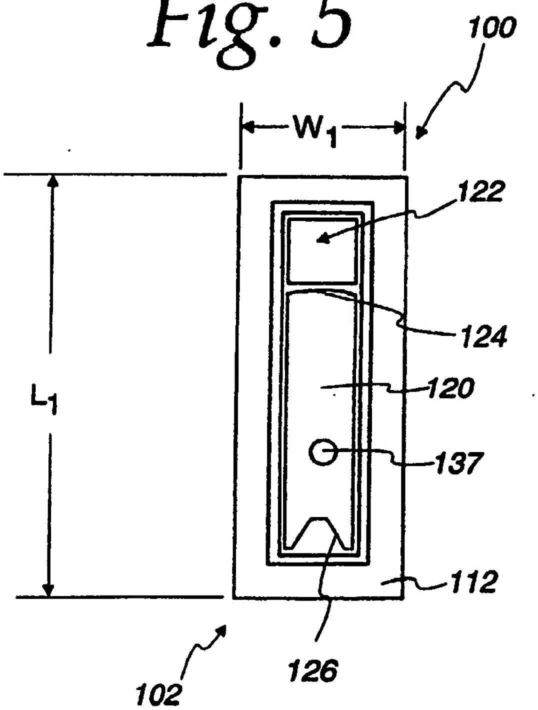



Fig. 6

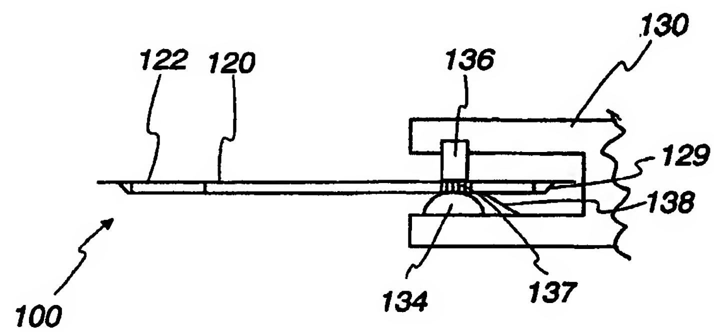



Fig. 7

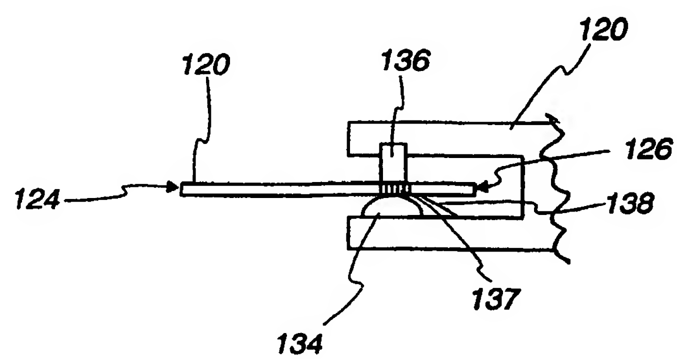


Fig. 8

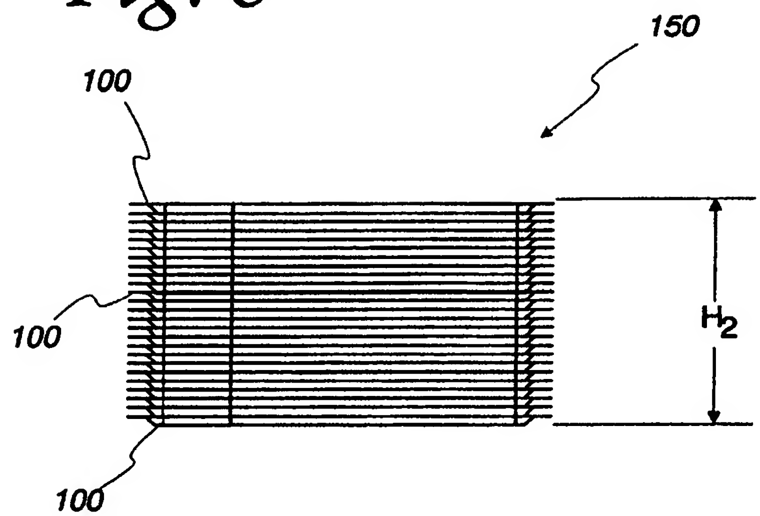
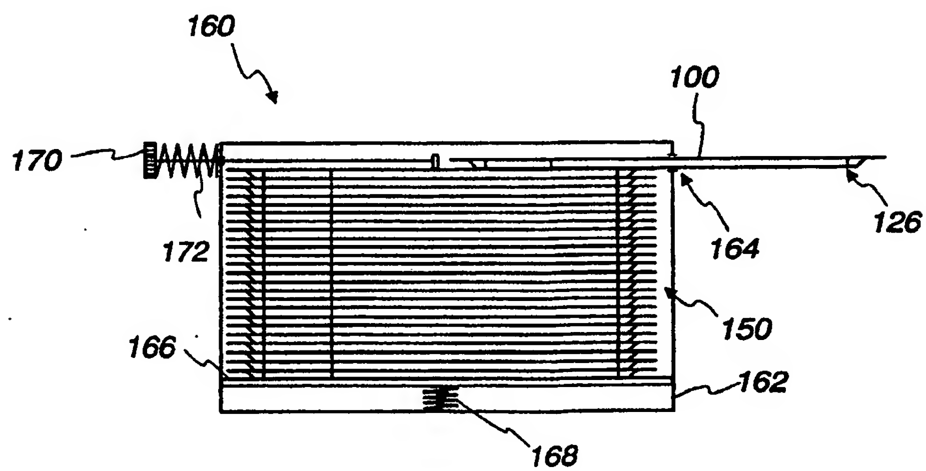



Fig. 9



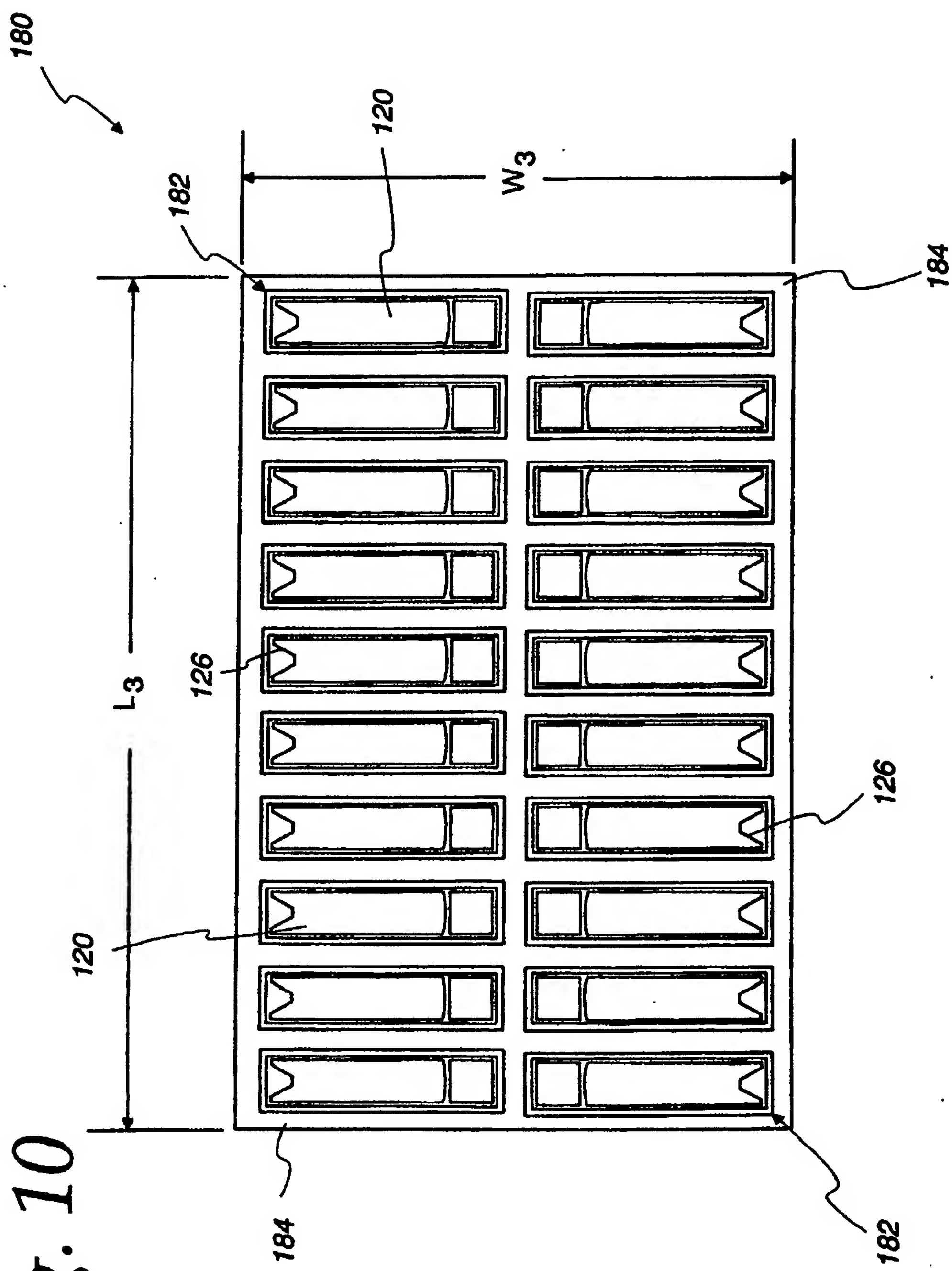



Fig. 10